

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 13-15, 18, 20, 26 and 28-30 are pending in this application. Claims 13, 18 and 26 have been amended for clarification. New claims 28-30 have been added. No new matter has been introduced.

Claim 13 has been amended to delete non-elected subject matter and to limit to the structures of those recited in claim 25. Specifically, claim 13 has been amended to clarify the structural features of the therapeutic agents as compounds of formula I-A, support for which is found, for example, page 9, tables I-III and Example G of the specification.

Claims 13 and 26 have been amended to delete the recitation of "prevention" with respect to osteoarthritis.

Claim 18 has been amended to depend on claim 15 rather than claim 17, as claim 17 has been cancelled. Support for claim 18 is found, for example, on page 9 and example G of the specification.

Claims 1-13, 16, 17, 19, 21-25 and 27 have been canceled.

New claims 28-30 have been added, each of which are dependent on claim 13 and further refine the genus thereof. As such, support for new claims 28-30 may be found, for example on page 9 of the specification and in claim 13 as currently amended.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

II. THE REJECTION UNDER 35 U.S.C. § 112, 1st PARAGRAPH IS OVERCOME

Claims 13-27 are rejected under 35 U.S.C. § 112, ¶1 as allegedly lacking reasonable enablement for (i) a method for prevention of osteoarthritis in a subject, comprising administering to the subject a therapeutically effective amount of a medicament comprising CPHPC, and (ii) a method for treatment or prevention of osteoarthritis in a subject, comprising administering to the subject a therapeutically effective amount of a medicament comprising an agent or a substituted or unsubstituted D-proline or stereoanalogue thereof.

Independent claims 13 and 26, and therefore all claims dependent thereon, have been amended to delete the recitation of “prevention” of osteoarthritis, thus being currently drawn to methods for treating osteoarthritis.

The therapeutic agent, D-proline or stereoanalogue thereof as recited in the previously presented claim set has been clarified to recite the structures of formula I-A. Enablement for the structures of formula I-A may be found, for example, in tables I-III and Example G of the specification. As such, it is respectfully submitted that enablement for the currently amended claim set is present in the specification. The Examiner is especially thanked for recognizing that the specification is enabling for a method for treatment of osteoarthritis in a subject, comprising administering to the subject a therapeutically effective amount of a medicament comprising CPHPC.

Claims 13-24 and 27 are rejected under 35 U.S.C. § 112, ¶1 as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention. Specifically, the Examiner contends that the claims are drawn to a method comprising administration of a structurally undefined genus of agents.

The claims have been amended to limit the claimed genus to those of formula I-A. The specification discloses, in Example G, the treatment of osteoarthritis with a compound of the formula I-A. The compound, CPHPC, is representative and provides the critical structural feature (two proline derivatives linked as amides through their respective N-termini). As such, the Applicant contends that the disclosure in the specification adequately supports the claim set as presented herein.

Further, as formula I-A provides sufficient recitation of distinguishing identifying characteristics, the skilled artisan may easily envision the detailed chemical structure (formula I-A) of the genus.

In view of the amendments and remarks presented herewith, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, paragraph 1 are thereby respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME

Claims 13 and 14 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brion, et al. (Osteoarthritis, Oxford Textbook of Medicine, 4th ed, vol. 3, (Warrell, et al, Eds.), Oxford University Press, Oxford, pp. 62-68, January, 2003) as further evidenced by Danielsen, et al. (Biochemica et Biophysica Acta 1339:73-78, 1997), hereinafter referred to as “Brion”.

The Examiner alleges that Brion teaches the treatment of osteoarthritis with chondroitin sulphate, a compound which is known to bind to SAP, thus meeting the limitations of claims 13 and 14.

Claim 13, and thus claim 14 which is dependent thereon, has been amended to limit the agents to compounds of formula I-A. The instant claims require compounds which are not disclosed for treatment of osteoarthritis in Brion. The subject matter of the instant claims is also not obvious to try based on the teachings of Brion or Danielsen, either alone or in combination, as neither of the references teach that the instantly claimed compounds may be used to treat osteoarthritis.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) with respect to Brion are respectfully requested.

IV. THE CLAIM OBJECTIONS ARE ADDRESSED

Claims 13-25 and 27 are objected to as reciting non-elected subject matter.

The claim set has been amended to delete the recitation of the non-elected subject matter. Specifically, claim 25 has been cancelled, and the remaining independent claims (claims 13 and 26) have been drawn to methods requiring compounds of general formula I-A, which was the subject matter elected in the Applicant's previous response.

Accordingly, reconsideration and withdrawal of the claim objections are respectfully requested.